



Food and Drug Administration Rockville MD 20857

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Re: FARESTON® Docket No. 97E-0357

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Stephen G. Kunin **Deputy Assistant Commissioner for** Patent Policy and Projects Office of the Assistant Commissioner for Patents U.S. Patent and Trademark Office Crystal Park Building 2, Suite 919 Washington, D.C. 20231

Dear Mr. Kunin:

This is in regard to the application for patent term extension for U.S. Patent No. 4,696,949 filed by ORION-YHTYMA OY under 35 U.S.C. § 156. The human drug product identified in the patent extension application is FARESTON®, which was assigned New Drug Application (NDA) No. 20-497.

A review of the Food and Drug Administration's official records indicates that this product was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. § 156(a)(4). Our records also indicate that it represents the first permitted commercial marketing or use of the product, as defined under 35 U.S.C. § 156(f)(1), and interpreted by the courts in Glaxo Operations UK Ltd. v. Quigg, 706 F. Supp 1224 (E.D. Va. 1989), affd, 894 F. 2d 392 (Fed. Cir. 1990).

The NDA was approved on May 29, 1997, which makes the submission of the patent term extension application on July 23, 1997, timely within the meaning of 35 U.S.C. § 156(d)(1).

Should you conclude that the subject patent is eligible for patent term extension, please advise us accordingly. As required by 35 U.S.C. § 156(d)(2)(A) we will then determine the applicable regulatory review period, publish the determination in the Federal Register, and notify you of our determination.

Please let me know if we can be of further assistance.

Sincerely,

Ronald L. Wilson, Director Health Assessment Policy Staff

Office of Health Affairs

Ronald J. Kubovcik CC: Kubovcik & Kubovcik 900 17th St. NW Suite 990 Washington, DC 20006